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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/869,275	06/04/1997	CARL T. WITTWER	T8616.CIP5	5556

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 03/27/2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/869,275

Applicant(s)
Wittwer et al.

Examiner
Ardin Marschel

Art Unit
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 22, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-35, 55-59, 79-82, 87-92, and 118-158 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration
- 5) ☒ Claim(s) 82, 87-92, 121-127, and 147-155 is/are allowed.
- 6) ☒ Claim(s) 13-35, 55-59, 79, 118, 128-146, and 156-158 is/are rejected.
- 7) ☒ Claim(s) 80, 81, 119, and 120 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☒ Interview Summary (PTO-413) ~~was not~~ certified copies
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Applicants' arguments, filed 6/22/01, have been fully considered and they are persuasive to overcome the previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application. The amendment, filed 6/22/01, has been entered. Due to the newly found rejections summarized below, the finality of the office action, mailed 4/23/01, is hereby withdrawn.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is limited to PCR process practice whereas in contrast the presently pending claims include generic biological reactions as claimed, for example, in claim 55.

Claims 13-35, 55-59, 128-146, and 156-158 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is firstly noted that the interpretation of the metes and bounds of means plus function language in claims is discussed at length in the MPEP in sections 2181-2186. It is also noted that

applicants' specification contains significant and lengthy discussion directed to the benefits in the instant invention of heating and/or cooling samples with a fluid with exemplifying air or a gas or, alternatively, heating with a lamp or with infrared radiation as summarized on page 42, lines 5-13, in the instant specification; versus the slower practice wherein a fluid such as water or mechanical heating blocks are utilized. A fluid is normally very well known to be defined in the art to include gaseous material as well as liquid material. One possible interpretation of these disclosures is that instant claim 13, lines 7 and 8, are limited to heating via air flow, gas flow, or infrared irradiation and cooling via air or gas flow via the above noted means plus function language in instant claim 13. This may also be the interpretation of claim 128, lines 7-8. Then claims 33 and 145, lines 9 and 10 in each claim, indicate that "hot fluid" is forced into contact with sample containers. It is noted that this wording is different from claim 13. Then claim 55 contains yet another wording set forth as "thermal cycling means for repeatedly heating and cooling..." in line 7 again without concisely indicating what means is meant. Claim 87, by way of contrast, clearly cites a "heater and a fan" in lines 4-5 for cycling temperature as does similarly claims 121, 122, 147, and 152; lines 3, 4, 4, and 4; respectively. These differing citations confuses the interpretation of said "means"

or fluid as to whether only gas or air is meant or whether fluids such as water may be included albeit discussed as being undesirable due to its low speed of heating or cooling in the practice of the instant invention. It is also noted that the claims are not required to heat or cool at any particular rate. No rapidity of heat exchange or thermal cycling is a claim limitation. Thus, it is confusing as to whether the claims are limited to gaseous type fluids or heating or cooling means with optional irradiation heating or whether liquid heating and/or cooling is available using water, for example. It is noted that the claims could be easily amended to cite these particular options so as to clearly define what is meant regarding "fluid" practice for heating or cooling. Clarification of the metes and bounds of the heating and cooling means and fluid metes and bounds via clearer claim wording is requested.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13, 14, 18, 20, 24, 25, 28, 31, 55-57, 118, 157, and 158 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Higuchi et al. [Bio/Technology 10:413(1992);

already of record].

Reconsideration of the priority dates for the instant claims reveals that the real time monitoring practice of the instant invention was not disclosed within a year after the date of publication of Higuchi et al. thus qualifying it as 102(b) prior art. Real time monitoring of PCR reactions with ethidium bromide fluorescence measurements are disclosed in the reference as a whole and shown in Figure 3 on page 414 as well as graphically regarding amount of reaction product. Figure 5 on page 415 also shows the real time monitoring of PCR product as well as discussed in the section entitled "Continuous monitoring of a PCR" on page 415. These disclosures anticipate the above instant claims. It is noted that only one side of the tubes are shown, for example, in Figure 4 on page 415 whereas the tubes have other sides as well as ends, albeit not of the rectilinear type of sides. The reaction tube size is given as 0.5 ml type in the Figure 3 legend on page 414.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which

the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 13, 14, 18, 20, 24, 25, 28, 31, 55, 79, 118, 157, and 158 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Linn et al. (P/N 5,800,989).

Linn et al. is directed in the title and abstract to amplification and detection via fluorescence polarization. The amplification types that are suggested and motivated for usage within the reference include a wide variety of such reactions as summarized in column 8, line 33, through column 9, line 36, which is noted to include PCR. Thus, the exemplification of tSDA does not limit the suggested amplification types in the reference. In column 14, line 39, through column 16, line 15, amplification is performed with the exemplified tSDA type of amplification to illustrate several details for amplification practice. A four position cuvette is utilized with a 800 microliter sample as set forth in column 14, lines 45-49, which is less than 1 milliliter. It is noted that more reaction materials are added but that the sample holder clearly holds less than 1 milliliter of sample and

also is rectangular with several sides given as 10 mm X 45 mm. The cuvette may be closed as noted in column 14, lines 55-57, during real time measurements of amplification. The cuvettes for sample measurement are placed in one of four holders in the spectrofluorometer. Thus, both means for positioning the sample container as well as manual control of such positioning is disclosed thereby. In Example 3 in column 14, lines 45-49, circulating water temperature control are means of heating and cooling as required in instant claim 13. The suggestion and motivation to perform real time monitoring of amplification as an option within the reference is set forth in column 5, lines 41-55, via several significant advantages. This exemplified amplification type along with the above noted PCR suggestion in the invention of Linn et al. suggests the usage of such a real time measuring methods and device for PCR amplifications also. It is recognized that the means for sample positioning and control thereof may be deemed to be via automation or device elements in the instant claims. In this case it is noted that automating a manual activity is deemed obvious as supported by the legal decision of *In re Venner* [262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)]. It is additionally noted that it is reasonably expected that a spectrofluorometer as described above would optimize excitation and detection practice as required in instant claim 20 including maximizing signal generation via light

path practice as required in instant claims 24, 25, 31, and 79. Regarding instant claim 79, a calculation of the cuvette dimensions with a 800 uL sample reveals that a 10 mm X 45 mm cuvette would be holding sample to a depth of 1.78 mm. If closed as noted above the external surface area would be 1095 mm². 800 uL equals 800 cubic mm. Therefore 800/1095 results in the ratio of volume to external surface area of 0.73 mm which meets the less than 1 mm ratio required in instant claim 79.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to perform PCR amplifications and monitor them in real time as instantly claimed given the above specific citations, suggestions, and motivation in Linn et al. or Linn et al. in combination with In re Venner, thus resulting in the practice of the instant invention.

The disclosure is objected to because of the following informalities:

In the specification on page 34, line 16, the specie name "aquatics" appears to be misspelled.

Appropriate correction is required.

Claims 80, 81, 119, and 120 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 82, 87-92, 121-127, and 147-155 are allowed.


Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

March 22, 2002


ARDIN H. MARSCHEL
PRIMARY EXAMINER